MAIL STOP APPEAL BRIEF-PATENTS
PATENT
3003-1159

IN THE U. S. PATENT AND TRADEMARK OFFICE

In re application of	Appeal No. Not assigned yet
Jeremy MARSHALL	Conf. 8360
Application No. 10/518,513	Group 3731
Filed: December 21, 2004	Examiner Kathleen C Sonnett
Title: LANCET	

APPEAL BRIEF

MAIL STOP APPEAL BRIEF-PATENTS
Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

MAY IT PLEASE YOUR HONORS:

1. REAL PARTY IN INTEREST

The real party in interest in this appeal is:

OWEN MUMFORD LIMITED, BROOK HILL, WOODSTOCK, OXFORD OX20, UNITED KINGDOM.

2. Related appeals and interferences

None.

3. Status of claims

Claims 1-11 have been canceled. Claims 12-20 are pending in the application and stand rejected, from which this appeal is taken.

4. Status of amendments

Per the interview result, the Amendment filed on November 12, 2010, which is subsequent to the Final rejection of May 5, 2010 should be entered. The claims at issue are thus set forth in the Amendment after Final of November 12, 2010.

5. Summary of claimed subject matter

Independent claim 12: As is set forth in independent claim 12, a lancet, including:

a needle (1) having a pointed tip (3) (Page 2, line 20);

a support body (2) enclosing the needle such that the pointed tip projects beyond the end of the support body (2) (Page 1, lines 19-20; Page 3, lines 12-14);

a removable guard (5) located over the pointed tip (3) of the needle (1) (Page 1, lines 19-20), the guard (5) having been integrally moulded from plastics material with the support body (2) and connected thereto by a breakable neck portion (15) (Page 1, lines 20-23; Page 2 lines 16-18);

the removable guard portion (5) having an outer peripheral thickened rib (10) describing a generally U- or C-shape (Page 1, lines 20-23; Page 2, lines 15-16), a central region of thinner section (11) than the rib (10) and partly surrounded by the rib (10) (Page 1, lines 20-23; Page 2, lines 8-9) and a further tip encasing region (13) encasing the tip of the needle (Page 2, lines 8-9), the tip encasing region (13) being of thicker section than the central region (11) and being spaced from adjacent ends of the peripheral thickened rib (10) such that there are respective gaps therebetween bridged only by the thinner central section (11) (Page 1, lines 20-23; Page 2, lines 8-9), the thinner central section (11) substantially surrounding the tip encasing region (13) and the tip (3) (Page 2, lines 10-14).

Independent claim 15: As is set forth in independent claim 15, a method of forming a lancet, including:

holding a needle (1) in a mould formed to create a support body (2) for holding the base portion of the needle and a removable guard (5) about the pointed needle tip (3) and to form a breakable neck portion (15) between the support body (2) and the guard (5) (Page 2, lines 19-21), the mould having an entry point (12) for plastics material, at the end of the guard remote from the needle point (Page 2, lines 21-

22), leading to an outer peripheral thickened hollow rib (10) of generally U- or C-shape which in turn leads to a thinner hollow section (10) approaching the needle tip (3) (Page 2, lines 23-24) and a further enlarged hollow region (13) encasing the needle tip (3) (Page 4, lines 8-9), the hollow region (13) encasing the needle tip (3) being of thicker section than the thinner hollow section (11) (Page 2, lines 8-9), the further enlarged hollow region (13) being spaced from adjacent ends of the peripheral thickened hollow rib (10) to leave respective gaps therebetween that is bridged by the thinner hollow section (10) (Page 4, lines 14-19), the thinner hollow section (10) substantially surrounding the enlarged hollow region (13) encasing the needle tip and the tip (3) (Page 2, lines 11-14); and

injecting plastics material into the mould via the entry point (12) to create the guard (5) about the needle tip (3) (Page 2, lines 25-26).

Independent claim 20: As is set forth in independent claim 20, a lancet, including:

a needle (1) having a pointed tip (3) (Page 3, line 13);

a support body (2) enclosing the needle (1) such that the pointed tip (3) projects beyond an end of the support body (2) (Page 1, lines 19-20; Page 3, lines 12-14);

a removable guard (5) located over the pointed tip (3) of the needle (1) (Page 1, lines 19-20), the guard (5) having been integrally moulded from plastics material with the support body (2) and connected thereto by a breakable neck portion (15) (Page 1, lines 20-23; Page 2 lines 16-18);

the removable guard portion (5) having an outer peripheral thickened rib (10) describing a generally U- or C-shape (Page 1, lines 20-23; Page 2, lines 15-16) with ends of the peripheral thickened rib (10) being disposed laterally adjacent the needle (Page 4, lines 4-5), a central region of thinner section (11) than the rib (10) and partly surrounded by the rib (10) and a further tip encasing region (13) encasing the tip (3) of the needle (Page 4, lines 4-5), the tip encasing region (13) being of thicker section than the central region (11) and being spaced from the adjacent ends of the peripheral thickened rib (10) such that there are respective gaps therebetween bridged only by the thinner central section (11) (Page 1, lines 20-23; Page 2, lines 8-9), the thinner central section (11) substantially surrounding the tip encasing region (13) and the tip (3) (Page 2, lines 10-14).

Dependent claim 13: Claim 13 differs from Claim 12 in its recitation that the guard is formed with a centrally positioned hole close to an end of the guard remote from the needle point (Page 1, line 27 bridging to Page 2, line 1).

Dependent claim 16: Claim 16 differs from Claim 15 in its recitation that the plastics material flows around both sides of a pin (9) located close to the entry point towards the edge thickened hollow region (Page 2, line 27 bridging to Page 3, line 2; Page 3, lines 16-19).

6. Grounds of rejection to be reviewed on appeal

The first ground for review on appeal is whether claims 18 and 20 are sufficiently duplicated in order to support an allegation of an objection under 37 CFR 1.75.

The second ground for review on appeal is whether claims 12, 14, 15, and 18-20 are sufficiently unpatentable over HIGGINS (US 3,358,689) in view of MORITA (US 5,628,765) in order to support an allegation of unpatentability under 35 U.S.C. 103(a).

The third ground for review on appeal is whether claims 13 and 17 are sufficiently unpatentable over HIGGINS in view of MORITA and CROSSMAN (GB 2,352,403) in order to

support an allegation of unpatentability under 35 U.S.C. 103(a).

The fourth ground for review on appeal is whether claim 16 is sufficiently unpatentable over HIGGINS in view of MORITA and CROSSMAN in order to support an allegation of unpatentability under 35 U.S.C. 103(a).

7. Argument

7.1 First Ground: double patenting

It is respectfully noted that claim 20 stands as an independent claim while claim 18 is a dependent claim that depends upon independent claim 12.

Further, claim 20 recites the position of the end of the peripheral thickened rib, namely "…ends of the peripheral thickened rib (10) being disposed laterally adjacent the needle…" Therefore, claims 18 and 20 set forth the present invention as different alternative embodiments which are not equivalent.

Accordingly, it is respectfully requested that this objection be withdrawn.

7.2 Second Ground: patentability over HIGGINS in view of MORITA

The present invention pertains to a lancet with a needle covered by a removable guard. The guard is formed from a moulded plastics material in a shape that alleviate the problem of the bending of the needle tip.

This can be seen in, for example, Figure 1 of the application, which is reproduced below.

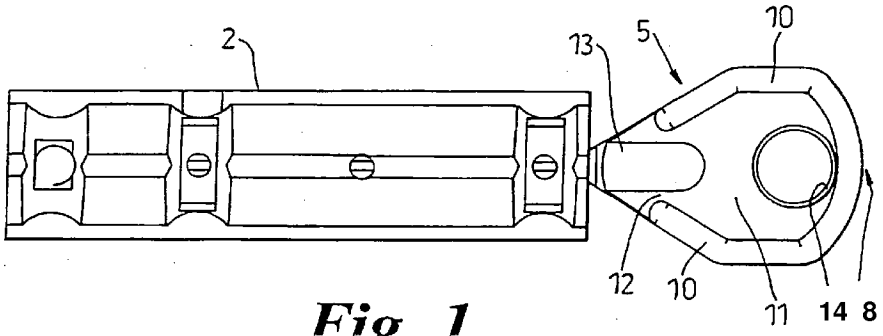


Fig. 1

The present invention addresses a problem that arises when injection moulding a releasable cap around the needle tip of the lancet. In order to reduce the pricking sensation in use, the lancet needle tip should be as fine as possible but this means that, unprotected, it can be inadvertently bent before use quite easily and thus can give problems to registration in an automatic finger pricking device and/or a diagnostic test strip etc.

Especially, the manufacturing process with the high pressures involved in injecting moulding, and due to

the relatively viscous nature of the molten plastics material, the in-rush of molten plastics material into the mould during the injection moulding process can deflect the needle tip out of its longitudinal and alignment.

In the present invention therefore the cross sections of the cap and the mould are carefully selected to ensure that the flow of molten plastic is temporarily slowed or choked before it passes into the part of the mould cavity which surrounds the needle tip.

Thus, as set out in claim 12, the removable guard portion has an outer peripheral thickened rib with a generally U- or C-shape. Also, a central region of thinner section than the rib and partly surrounded by the rib and a further tip encasing region encasing the tip of the needle. **The tip encasing region has a thicker section than the central region and is spaced from adjacent ends of the peripheral thickened rib such that there are respective gaps therebetween bridged only by the thinner central section.**

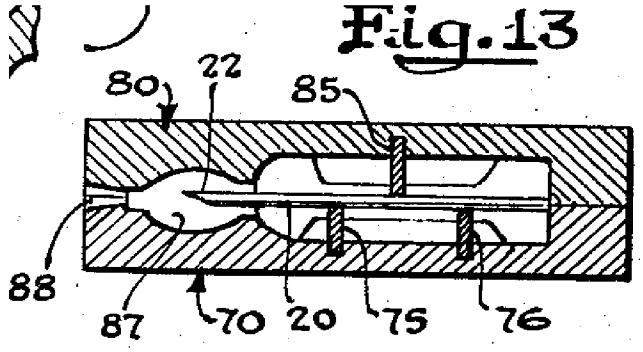
This means that the in-rush of molten plastics material into the outer peripheral region is **unexpectedly slowed** by the thinner bridging region before it reaches the further enlarged region, thus minimising the possibility of damage to the needle.

The Office acknowledges that HIGGINS does not disclose the claimed peripheral thickened rib but asserts that one skill in the art would achieve the present invention by adding the rib of MORITA to the lancet of HIGGINS because it facilitates gripping of the guard.

However, the respective **gap** bridged between the peripheral thickened rib and the tip encasing region have not been disclosed or suggested by neither HIGGINS nor MORITA.

HIGGINS pertains to be an integral lancet and a method to manufacture the integral lancet. Figures 10 and 13, which are referred to by the Office, are reproduced below. Additionally, Figure 1 is also reproduced to illustrate the final product made by the mold of Figure 13.

The molten plastic material pushes the needle to the bottom



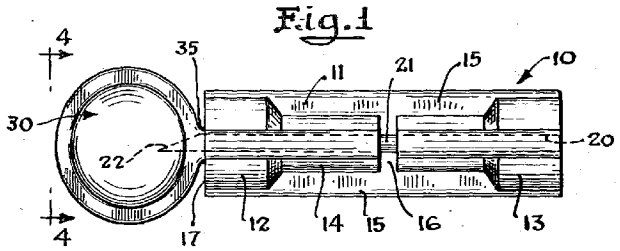
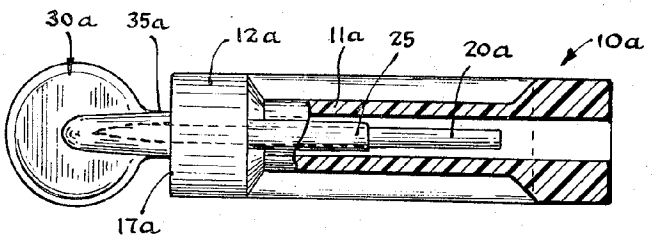


Fig.10



From Figure 13, it can be seen that the needle is supported by the insert plates 75, 76 and 85. Then, the molten material is injected in to the cavity 87 through the gate 88 with a pressure to force the lancet 20 into engagement with the rear wall of the mold cavity 87. (*See Column 4, lines 53-64 of HIGGINS.*)

That is, the molten material has to be **rapidly**, i.e. forcefully, injected into the mold cavity 87. If the speed of the molten material around the tip of the needle 22 is slow down by an unsmooth shape of the cap section 30, i.e. a gap, the molten material will only accumulate around the tip of the needle without pushing the lancet 20 back forward.

Even in the alternative embodiment, Figure 10, the lancet 20a is frictionally engaged with a small diameter axial sleeve section 25. (*See Column 3, lines 44-47 of HIGGINS.*) The injecting pressure still requires overcoming the viscous nature of the molten plastics material. HIGGINS thus at least is silent about injecting

the molten material slowly specifically around the tip of the lancet 20a.

The Office also refers to Figures 10 and 11 of MORITA, which are reproduced below.

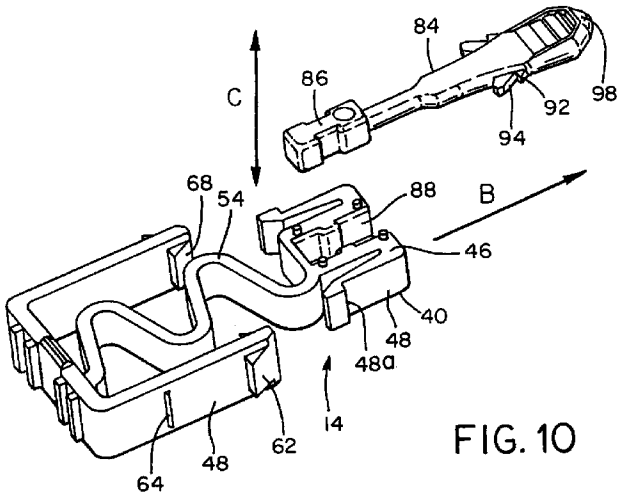


FIG. 10

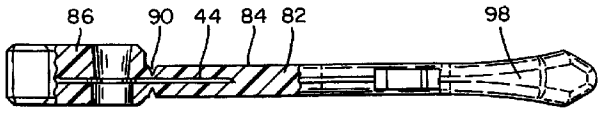


FIG. 11

Looking at the purported combination of MORITA with HIGGINS, the assertion that it would be obvious to add the slightly thickened peripheral rib of MORITA to the arrangement of HIGGINS would not occur to one of ordinary skill.

With its T-formation the device already gives plenty of grip. Also the applicant can find no discussion in MORITA of the edge region enhancing the grip, as suggested in the Office, and the skilled person would have

no reason to take this feature from MORITA. Indeed, MORITA makes no mention of the shape.

Even if a peripheral rib concept were applied to MARSHALL et al., the natural design would be to extend the peripheral rib so that it merged with the stem of cap member 30 of HIGGINS. In other words, by combining MORITA and HIGGINS, the resultant combination would be one which still failed to set forth the important feature that the ends of the peripheral region are spaced from the tip encasing regions by the regions of thinner section.

The rejection therefore should be withdrawn.

7.3 Third Ground: patentability over HIGGINS in view of MORITA and CROSSMAN

CROSSMAN is relied upon solely for having a hole formed in the distal end of plastic injection-molded gaurs. Figures 1-3, which are referred to by the Office, are reproduced below.

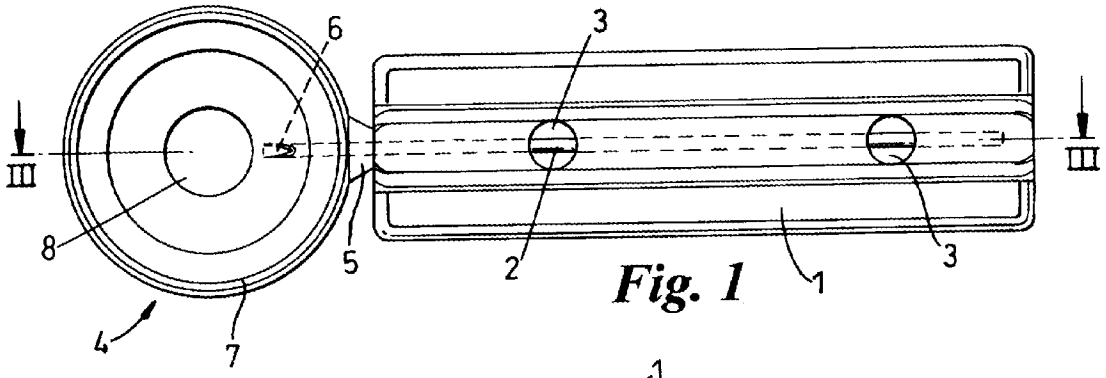


Fig. 1

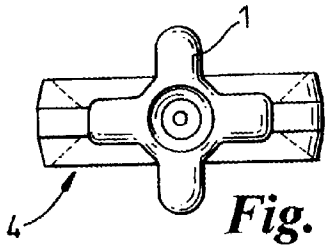


Fig. 2

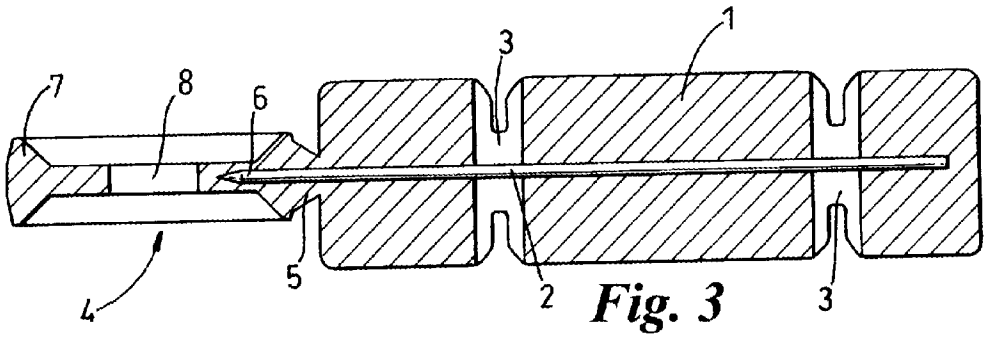


Fig. 3

However, claim 13 recites that: “guard is formed with a centrally positioned hole close to an end of the guard remote from the needle point”.

With the hole 9 of the present invention, the flow of the molten plastics material is been balanced and such that the needle is not bent.

As such, CROSSMAN provides nothing that would bring the more basic proposed combination of HIGGINS and

MORITA closer to the invention as recited in the independent claims 12, 15 and 20. Also, HIGGINS, MORITA and CROSSMAN, in combine or singular, would not teach or suggest the one skill in the art to have the claimed hole.

The rejection of claims 13 and 17 should therefore also be reversed at least by virtue of the dependency of those claims from allowable independent claims.

7.4 Fourth Ground: patentability over HIGGINS in view of MORITA and CROSSMAN

As noted in the above discussion of the third ground of rejection, CROSSMAN does not teach a pin positioned close to the end of the guard remote from the needle point, as recited in claim 16, contrary to the characterization in the final rejection.

As such, CROSSMAN provides nothing that would bring the more basic proposed combination of HIGGINS and MORITA closer to the invention as recited in the independent claim 15. Also, HIGGINS, MORITA and CROSSMAN, in combine or singular, would not teach or suggest the one skill in the art to have the claimed hole.

The rejection of claim 16 should therefore also be reversed at least by virtue of the dependency of those claims from allowable independent claims.

8. Conclusion

The Appellant has demonstrated that the Examiner has failed to successfully allege that the rejected claims are *prima facie* unpatentable. It is clear that the inventive lancet has advantages unseen over the applied art. For the reasons advanced above, it is respectfully submitted that all the rejected claims in this application are allowable. Thus, favorable reconsideration and reversal of the rejection under double patenting and 35 USC §103, by the Honorable Board of Patent Appeals and Interferences, are respectfully solicited.

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The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/Robert E. Goozner/

Robert E. Goozner,Reg.No.42,593
Attorney for Appellant
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573

REG/hc/fb

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9. Claims Appendix

12. A lancet, comprising:

a needle having a pointed tip;

a support body enclosing the needle such that the pointed tip projects beyond the end of the support body;

a removable guard located over the pointed tip of the needle, said guard having been integrally moulded from plastics material with said support body and connected thereto by a breakable neck portion;

said removable guard portion having an outer peripheral thickened rib describing a generally U- or C-shape, a central region of thinner section than said rib and partly surrounded by said rib and a further tip encasing region encasing the tip of the needle, the tip encasing region being of thicker section than said central region and being spaced from adjacent ends of the peripheral thickened rib such that there are respective gaps therebetween bridged only by said thinner central section, said thinner central section substantially surrounding said tip encasing region and the tip.

13. The lancet according to claim 12, wherein the guard is formed with a centrally positioned hole close to an end of the guard remote from the needle point.

14. The lancet according to claim 12, wherein the guard is of generally tab-like form, with the thickened rib forming arc-like portions on two side edges of the guard which lead to the thinner section of plastics material adjacent to the needle tip.

15. A method of forming a lancet, comprising:

holding a needle in a mould formed to create a support body for holding a base portion of the needle and a removable guard about a pointed needle tip and to form a breakable neck portion between the support body and the guard, the mould having an entry point for plastics material, at an end of the guard remote from the needle point, leading to an outer peripheral thickened hollow rib of generally U- or C-shape which in turn leads to a thinner hollow section approaching the needle tip and a further enlarged hollow region encasing the needle tip, the hollow region encasing the needle tip being of thicker section than said thinner hollow section, the further enlarged hollow region being spaced from adjacent ends of the peripheral thickened hollow rib to leave respective gaps therebetween that are bridged by said thinner hollow section, the thinner hollow section substantially

surrounding said enlarged hollow region encasing the needle tip and the tip; and

injecting plastics material into the mould via the entry point to create the guard about the needle tip.

16. The method according to claim 15, wherein the plastics material flows around both sides of a pin located close to said entry point towards said edge thickened hollow region.

17. The lancet according to claim 13, wherein the guard is of generally tab-like form, with the thickened rib forming arc-like portions on two side edges of the guard which lead to the thinner section of plastics material adjacent to the needle tip.

18. The lancet according to claim 12, wherein the ends of the peripheral thickened rib are disposed laterally said needle.

19. The method according to claim 15, wherein the ends of the peripheral thickened rib are disposed laterally said needle.

20. A lancet, comprising:

a needle having a pointed tip;

a support body enclosing the needle such that the pointed tip projects beyond an end of the support body;

a removable guard located over the pointed tip of the needle, said guard having been integrally moulded from plastics material with said support body and connected thereto by a breakable neck portion;

said removable guard portion having an outer peripheral thickened rib describing a generally U- or C-shape with ends of the peripheral thickened rib being disposed laterally adjacent said needle, a central region of thinner section than said rib and partly surrounded by said rib and a further tip encasing region encasing the tip of the needle, the tip encasing region being of thicker section than said central region and being spaced from the adjacent ends of the peripheral thickened rib such that there are respective gaps therebetween bridged only by said thinner central section, said thinner central section substantially surrounding said tip encasing region and the tip.

10. Evidence Appendix

None.

11. Related Proceedings Appendix

None.